

**IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF GEORGIA
ATLANTA DIVISION**

HEALTHIER CHOICES
MANAGEMENT CORP.,

Plaintiff,

v.

PHILIP MORRIS USA, INC. and PHILIP
MORRIS PRODUCTS S.A.,

Defendants.

Case No. 1:20-cv-04816-TCB

**DEFENDANTS' MEMORANDUM IN SUPPORT OF THEIR
MOTION TO DISMISS UNDER FED. R. CIV. P. 12(b)(6)**

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I. INTRODUCTION

Most patent cases are not amenable to a decision on the merits at the pleading stage. This case is an exception to that general rule and requires the Court’s early attention to prevent wasteful litigation of a groundless infringement claim.

Plaintiff Healthier Choices Management Corp. (“HCMC” or Plaintiff) has asserted a patent that expressly *requires “combustion”* against an innovative “heat-not-burn” IQOS® device developed by Defendant Philip Morris Products S.A. (“PMP”) and distributed by Defendant Philip Morris USA, Inc. (“PMUSA,” collectively with PMP, “Defendants”)—that is specifically engineered so that *“combustion” cannot occur*. Indeed, the very exhibit that Plaintiff exclusively relies on to support its allegation that IQOS combusts tobacco conclusively establishes just the opposite. Exhibit J to the Complaint is the Executive Summary of PMP’s Modified Risk Tobacco Product Application (“MRTPA”) that was submitted to the U.S. Food and Drug Administration (“FDA”).¹ It establishes that

¹ The IQOS System when used with a tobacco stick (hereinafter, “IQOS”) is one of the very rare products subject to the Tobacco Control Act of 2009 (“TCA”) that has received FDA authorization. IQOS has received two Premarket Tobacco Product Application (“PMTA”) authorizations, which are required to lawfully sell products subject to the TCA. Also, in July 2020, IQOS became just the second product – and only aerosol delivery system – to receive authorization as a Modified Risk Tobacco Product (“MRTPA”), which is premised on the FDA’s finding that the sale of IQOS in the U.S. would be “appropriate to promote the public health and is expected to

IQOS heats but does not burn or combust tobacco, and it is designed so that its heater cannot even approach combustion temperatures. Consequently, Plaintiff's pleadings (which include exhibits to the Complaint) conclusively establish that IQOS does not and cannot infringe the asserted patent.

Dismissal with prejudice is warranted and just under these circumstances. Plaintiff is entitled only to have *reasonable* inferences drawn in its favor, not an unreasonable inference that is refuted by the FDA document attached to the Complaint. And because Plaintiff's theory is implausible on the merits, no amended pleading can cure its shortcomings.

Dismissal is warranted on Plaintiff's indirect infringement claims for a separate and independent reason. To allege indirect infringement, the patent law requires a plaintiff to plausibly allege that Defendants had pre-suit knowledge of the asserted patents. Rather than allege knowledge, Plaintiff speculates that Defendants "knowingly" induced and contributed to infringement, without any supporting factual allegations. For this independent reason, dismissal of Plaintiff's indirect infringement claims is required.

benefit the health of the population as a whole." SCIENTIFIC REVIEW OF MODIFIED RISK TOBACCO PRODUCT APPLICATION (MRTPA) UNDER SECTION 911(D) OF THE FD&C ACT (attached as Ex. 1, at 74 "FDA Scientific Review").

II. STANDARD OF REVIEW

A. Motion to Dismiss for Failure to State a Claim

To survive a motion to dismiss under Rule 12(b)(6), the factual allegations pled must “plausibly suggest[] (not merely [be] consistent with)” the conduct required to establish the cause of action. *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 545 (2007). This plausibility requirement applies to “all the elements of the claim for relief.” *Feldman v. Am. Dawn, Inc.*, 849 F.3d 1333, 1339 (11th Cir. 2017) (citing *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009)). Thus, a plaintiff must plead “factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged.” *Iqbal*, 556 U.S. at 678. Further, “the tenet that a court must accept as true all of the allegations contained in a complaint is inapplicable to legal conclusions.” *Id.* Similarly, “threadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice.” *Id.*

In evaluating a 12(b)(6) motion:

[C]ourts must consider the complaint in its entirety, as well as other sources courts ordinarily examine when ruling on Rule 12(b)(6) motions to dismiss, in particular, documents incorporated into the complaint by reference, and matters of which a court may take judicial notice.

Tellabs, Inc. v. Makor Issues & Rights, Ltd., 551 U.S. 308, 322 (2007). Attachments to the Complaint are “part of the pleading for all purposes.” FED. R. CIV. P. 10(c).

Importantly, courts must “treat specific facts demonstrated by exhibits as overriding more generalized or conclusory statements in the complaint itself.” *F.T.C. v. AbbVie Prods. LLC*, 713 F.3d 54, 63 (11th Cir. 2013) (citing *Griffin Indus., Inc. v. Irvin*, 496 F.3d 1189, 1206 (11th Cir. 2007)). Indeed, “when the exhibits contradict the general and conclusory allegations of the pleading, *the exhibits govern.*” *Griffin*, 496 F.3d at 1206.²

B. Legal Standards Applicable to Infringement

“To prove direct infringement, the plaintiff must establish by a preponderance of the evidence that one or more claims of the patent read on the accused device literally or under the doctrine of equivalents.” *Cross Med Prods. v. Medtronic Sofamor Danek, Inc.*, 424 F.3d 1293, 1310 (Fed. Cir. 2005). “Literal infringement requires that each and every limitation set forth in a claim appear in the accused product.” *Franks Casing Crew & Rental Tools, Inc. v. Weatherford Int’l, Inc.*, 389 F.3d 1370, 1378 (Fed. Cir. 2004). “Infringement under the doctrine of equivalents requires the patentee to prove that the accused device contains an equivalent for each limitation not literally satisfied.” *Wi-Lan, Inc. v. Apple Inc.*, 811 F.3d 455, 463 (Fed. Cir. 2016). “Indirect infringement, whether inducement to infringe or contributory

² All emphasis added and citations omitted unless otherwise noted.

infringement, can only arise in the presence of direct infringement.” *Dynacore Holdings Corp. v. U.S. Philips Corp.*, 363 F.3d 1263, 1272 (Fed. Cir. 2004). As with any other cause of action, implausible patent infringement claims are properly dismissed under Rule 12(b)(6). *See Amgen Inc. v. Coherus Biosciences Inc.*, 931 F.3d 1154, 1161 (Fed. Cir. 2019); *Ottah v. Fiat Chrysler*, 884 F.3d 1135, 1141-42 (Fed. Cir. 2018).

To plead indirect infringement, a complaint must allege that “the Defendant[s] must have known that the patent existed,” and had knowledge of their infringement. *Swipe Innovations, LLC v. NCR Corp.*, No. 1:13-CV-2219-TWT, 2013 WL 6080439, at *2 (N.D. Ga. Nov. 18, 2013) (dismissing indirect infringement claims for failing to adequately allege pre-suit knowledge). Specifically, to state a plausible claim for induced infringement under 35 U.S.C. § 271(b), “the accused infringer must have knowingly and intentionally induced another party's direct infringement.” *Merial Ltd. v. Cipla Ltd.*, 681 F.3d 1283, 1304 (Fed. Cir. 2012). And to state a plausible claim for contributory infringement under 35 U.S.C. § 271(c), “the Defendant[s] must have known that the combination that its product was incorporated into was patented and infringing.” *Swipe Innovations*, 2013 WL 6080439, at *4.

III. RELEVANT PROCEDURAL AND FACTUAL BACKGROUND

A. The Asserted '170 Patent

Plaintiff sued on November 30, 2020. The sole cause of action alleged is infringement of U.S. Patent Number 10,561,170 (“the ’170 patent”). Doc. 1 ¶¶ 38-59.

The ’170 patent, titled “Electronic Pipe,” was filed on March 16, 2018 and issued on February 18, 2020. Doc. 1-1 at 1. The specification of the ’170 patent describes an “electronic pipe” that includes a battery, heating wire, and reservoir of combustible material, in which “[t]he heating wire is designed to heat to a temperature sufficient to ignite a combustible material.” *Id.* at (4:54-56). According to the patent, electricity flows from the battery to the heating wire, causing it to “ignite the combustible material.” *Id.* at (4:7; 5:63).

The ’170 patent contains two independent claims, claims 1 and 5.³ Both independent claims require “initiating a combustion reaction.” Claim 1 is an apparatus claim that recites the following limitations:

³ All remaining claims in the ’170 patent are dependent claims, meaning they depend on, and add limitations to, independent claims 1 or 5. Consequently, if an accused infringer does not infringe an independent claim, it cannot infringe the dependent claims associated with that independent claim. 35 U.S.C. § 112(d) (“A claim in dependent form shall be construed to incorporate by reference all the limitations of the claim to which it refers.”).

An electronic pipe, comprising:

a battery, an electronic module, a combustible material reservoir, and a heating element fixed in the combustible material reservoir;

combustible material loaded into the combustible material reservoir;

wherein the pipe is structured to transmit an electric current from the battery to the heating element, the heating element ***initiating a combustion reaction*** in the combustible material reservoir.

'170 patent (9:36-10:4).

Claim 5 is a method claim that recites the following steps:

A method of at least partially combusting a combustible material for inhalation, comprising:

providing an electronic pipe comprising a battery, an electronic module, a combustible material reservoir, and a heating element fixed in the combustible material reservoir;

loading the combustible material into the combustible material reservoir;

activating the electronic pipe such that electric current is transmitted from the battery to the heating element;

initiating, by way of the heating element, a combustion reaction in the combustible material reservoir, the combustion reaction at least partially combusting the combustible material.

'170 patent (10:15-29). As the emphasized language demonstrates, both independent claims of the '170 patent—and thus all claims—requires “initiating a combustion reaction.”

To be sure, the '170 patent confirms that “combustion reaction” means exactly what it says – the combustible material is heated to a temperature that causes it to *ignite* and *burn*. *See id.* at 3:12-13 (“As shown in FIG. 1, a heating net 135 is provided for holding and *burning a combustible material* such as tobacco.”); 4:2-8 (stating that the heating wire “receives electricity from the rechargeable battery 120 to thereby heat the heating net 135 and *ignite the combustible material* located in the heating net 135”); 4:17-18 (“The tobacco, or other ignitable material therein *will then be ignited.*”); 4:52-58 (“In the embodiment illustrated in FIG. 2, a heating wire 160 is employed for heating the tobacco, or any other desired combustible material. The heating wire 160 is designed to heat to a *temperature sufficient to ignite a combustible material* that is placed in the combustible material reservoir 165....”); 5:61-63 (“...the heating wire 160 receives electricity from the rechargeable battery 120 to thereby heat the heating wire 160 and *ignite the combustible material* located in the combustible material reservoir 165”); 6:4-5 (“The tobacco, or other ignitable material therein will then be *ignited.*”).

The '170 patent supports no other colorable interpretation of “combustion reaction.”

B. HCMC’s Direct Infringement Allegations

HCMC contends Defendants infringe at least claims 1 and 5 of the ’170 patent through various activities relating to the importation and sale of IQOS. Doc. 1 ¶¶ 38-59. Per the Complaint, IQOS is “a ‘heat-not-burn’ tobacco system” with three principal components: “(1) a Tobacco Stick that is ‘designed to function with the holder’; (2) a Holder into which the Tobacco Stick is inserted and heated; and (3) a Charger that is used to recharge the Holder after each use.” *Id.* ¶ 26 (quoting Ex. J). In attempting to align IQOS’s features with the requirements of claims 1 and 5 of the ’170 patent, Plaintiff relies almost exclusively on Exhibit J—the MRTPA. *Id.* ¶¶ 26, 29, 43-46, 50-52.

With respect to the claim limitations relevant to this Motion—*i.e.*, the requirement that (i) the device of claim 1 be structured so that the “heating element initiat[es] a combustion reaction;” and (ii) the step in claim 5 of “initiating...a combustion reaction”—the following two sentences from the MRTPA are the only allegations Plaintiff makes: “the THS [Tobacco Heating System] aerosol contains substantially lower levels of HPHCs [Harmful and Potentially Harmful Constituents] compared to cigarette smoke. Importantly, nitrogen oxides (NO_x) and carbon monoxide (CO), two important combustion markers, were reduced by over 97%.” *Id.* ¶ 46 (quoting Exh. J at 40-41), ¶ 52 (same). From this, Plaintiff alleges

in a conclusory manner that “the presence of 3% of the two important combustion markers nitrogen oxides and carbon monoxide indicates that at least some combustion occurs when the Accused Infringing Product is operated as designed and intended by Defendants.” *Id.* ¶ 46; ¶ 52 (same).

As explained below, Exhibit J refutes Plaintiff’s conclusory allegation of “combustion.” Consequently, because “[Exhibit J] contradict[s] the general and conclusory allegations of [Plaintiff’s Complaint], *the exhibits govern.*” *Griffin*, 496 F.3d at 1206.

C. Exhibit J’s Statements About Combustion

The two sentences Plaintiff cites in Exhibit J are not the only portions of the document that address whether combustion occurs in an IQOS device. Instead, Exhibit J addresses combustion at length, and in so doing not only repeatedly states that combustion does not occur in IQOS (“IQOS” is referred to in the MRTPA as “THS”), but also explains why combustion *cannot* occur.⁴ *See, e.g.*, Doc. 1-10 at 19 (“*No combustion takes place in THS...*”); 20 (“THS generates a nicotine-containing aerosol by heating the tobacco in a manner that *avoids combustion.*”); 23

⁴ The 200-page MRTPA summary was based on PMP’s extensive, multi-year, scientific analysis of IQOS, which included detailed epidemiological data and ran over one million pages.

(“The *tobacco never ignites or burns*...THS heats tobacco to *temperatures below the level of combustion*...”); 40 (“The highest observed temperature of the tobacco in the Tobacco Stick is approximately 300°C (measured 0.2 mm from the heater blade) and *cannot exceed 350°C (the programmed maximum temperature of the heater)* (Figure 9). This is *well below the temperature required for tobacco combustion*...”); 41 (“*Since combustion does not occur*, the structural integrity of the Tobacco Stick is retained after use. The tobacco is not consumed, as it is in a cigarette, and no ash is formed.”).

Exhibit J also describes extensive testing of IQOS that PMP submitted to the FDA and that confirms that combustion cannot occur. Exhibit J explains that in one experiment “PMI tested THS in a chamber with air and in a chamber filled only with nitrogen, where one of the essential elements of combustion (oxygen) was absent.” *Id.* at 41. The result: “[t]he aerosol was equivalent under both atmospheres.” *Id.* Exhibit J also explains that puff testing of IQOS shows marked temperature decreases every time a user puffs—the exact opposite of what would occur if combustion were occurring. *Id.* at 40 (“During a [conventional cigarette] puff, the temperature *increases* to more than 900 °C...”).

Likewise, testing shows that “when the energy source is switched off, the temperature of the tobacco begins to decrease,” which is inconsistent with what

would happen in the “self-sustaining [combustion] process.” *Id.* at 41. Finally, the testing described in Exhibit J establishes that “the THS aerosol does not contain solid particles” associated with cigarette smoke, and—as noted above—unambiguously states that the IQOS heater cannot reach the temperature required for combustion. *Id.* at 40-41. Plaintiff does not address—much less explain—any of this language from Exhibit J to the Complaint.

D. The FDA’s Confirmation of Exhibit J’s Findings

The Complaint correctly alleges that on April 30, 2019 “the FDA authorized PMP” to market and sell IQOS. Doc. 1 ¶ 34. After that authorization, the FDA conducted a “Scientific Review” of the MRPTA application that evaluated specific claims made in the MRPTA, including the claim that IQOS® “heats tobacco but does not burn it.” *See* SCIENTIFIC REVIEW OF MODIFIED RISK TOBACCO PRODUCT APPLICATION (MRTPA) UNDER SECTION 911(D) OF THE FD&C ACT (attached as Ex. 1, “FDA Scientific Review”).⁵ The FDA’s Scientific Review was unambiguous in its conclusion that there is no combustion:

After conducting a thorough assessment of the scientific evidence, *I find that “the IQOS system heats tobacco but does not burn it,”* “this significantly reduces the production of harmful and potentially harmful chemicals,” and “scientific studies have shown that switching

⁵ The FDA Scientific Review is publicly available for download on the FDA’s website. *See* <https://www.fda.gov/media/139796/download>.

completely from conventional cigarettes to the IQOS system significantly reduces your body's exposure to harmful or potentially harmful chemicals."

FDA Scientific Review at 11.

The FDA's Scientific Review went on to examine and validate all of the scientific data presented in the MRPTA regarding the absence of combustion in IQOS. For example, it found that "[t]he applicant provided detailed information on the verification of heating blade temperature and quantitative thermal analysis using infrared thermography, demonstrating that the temperature does not exceed 350°C," and that "[t]he *combustion of combusted cigarettes typically occurs between 470–812 °C, which is well above the maximum temperature of the IQOS system.*" *Id.*

at 20. The FDA's ultimate conclusion after evaluating all of the data was as follows:

The low temperature in the IQOS system ($\leq 350^{\circ}\text{C}$), the lack of an exothermic process, the similar levels of HPHCs in the presence and absence of oxygen, and the low level of nitrogen oxides in the aerosol of the IQOS system with Heatsticks suggest that combustion does not occur in the IQOS system with Heatsticks when it is used as intended. ***There is sufficient evidence to support the following statement: The IQOS system heats tobacco but does not burn it.***

FDA Scientific Review at 21 (emphasis original).

Although not attached to the Complaint, the Court may take judicial notice of the FDA Scientific Review. In evaluating a 12(b)(6) motion, "[t]he court is not limited to the four corners of the complaint" and instead may consider "matters

incorporated by reference or integral to the claim, items subject to judicial notice, *matters of public record*, orders, items appearing in the record of the case, and exhibits attached to the complaint whose authenticity is unquestioned.” 5B Wright & A. Miller, FED. PRAC. & PROC. CIV. § 1357 (3d ed.). Critically, “[t]hese matters are deemed to be a part of every complaint by implication” and thus “may be considered by the district judge without converting the motion into one for summary judgment.” *Id.*; *Brown v. Wells Fargo Bank, N.A.*, 2018 WL 6694921, at 2 (N.D. Ga. Dec. 3, 2018) (Batten, J.) This principle is reflected in the Rules of Evidence, which authorize courts “at any stage of the proceeding” to take judicial notice of facts that “can be accurately and readily determined from sources whose accuracy cannot reasonably be questioned.” FED. R. EVID. 201(b)-(d).

Public records of government agencies such as the FDA are precisely the type of unquestionably accurate source that courts routinely judicially notice. *See Funk v. Stryker Corp.*, 631 F.3d 777, 783 (5th Cir. 2011) (“[W]e hold that it was appropriate for the court to take judicial notice, under Rule 12(b)(6), of the PMA the FDA granted to Stryker for marketing its Trident System.”); *Bryant v. Avado Brands, Inc.*, 187 F.3d 1271, 1280-81 (11th Cir. 1999) (directing district court to

“take judicial notice of relevant public documents required to be filed with the SEC” in evaluating Rule 12(b)(6) motion).⁶

E. HCMC’s Indirect Infringement Allegations

Plaintiff alleges, in conclusory fashion, that Defendants “had knowledge of Plaintiff’s assertion of infringement of the ’170 patent” and therefore “knowingly, actively induced” and “knowingly contributed to” the infringement of the ’170 patent. *Id.*, ¶¶ 55, 56. The Complaint fails to allege any facts that would support that conclusory allegation such as, for example, an allegation that Plaintiff gave Defendants notice of the alleged infringement before suit. But there is no allegation that Defendants knew of the existence of the ’170 patent prior to the Complaint, much less had notice of any infringement claim by Plaintiff.

IV. HCMC’S DIRECT INFRINGEMENT CLAIMS SHOULD BE DISMISSED WITH PREJUDICE

To prevail on its infringement claim, Plaintiff must show by a preponderance of the evidence that IQOS “initiates a combustion reaction.” In light of Exhibit J’s repeated statements that IQOS does not burn tobacco—and the FDA’s confirmation

⁶ On February 12, 2021, PMP sent a detailed letter to Plaintiff, notifying it of the facts set out in this Section III, and including a detailed declaration explaining why there is no combustion in the accused IQOS product, and why Plaintiff’s allegations lack Rule 11 basis as of that date.

of the same—Plaintiff’s allegations fail as a matter of law. As explained below, this is precisely the type of speculative, implausible claim that controlling precedent confirms should be eliminated at the outset of a case. Defendants should not be forced to expend resources defending against a claim that is definitively and expressly refuted by Plaintiff’s own exhibits to its Complaint.

A. Exhibit J Establishes that Plaintiff’s Direct Infringement Claims are Implausible

Exhibit J definitively, expressly, and repeatedly refutes Plaintiff’s conclusory allegation that use of IQOS “results in combustion of at least a portion of the IQOS® Tobacco Stick”—an allegation that is essential to Plaintiff’s infringement claim.

Doc. 1 ¶ 46. Instead, Exhibit J states the opposite:

To operate the THS product, the user inserts a Tobacco Stick into the holder and turns on the device by means of a switch. This initiates the heating of the tobacco via the heating blade inserted into the tobacco plug. *The tobacco neither ignites nor burns.* The electronically controlled heating, in combination with the uniquely processed tobacco, *prevents combustion from occurring* (Section 2.7.5).

Doc. 1-10 at 23; *see also id.* at 19 (“*No combustion takes place* in THS...”); 20 (“THS generates a nicotine-containing aerosol by heating the tobacco in a manner that *avoids combustion.*”); 41 (“*Since combustion does not occur*, the structural integrity of the Tobacco Stick is retained after use. *The tobacco is not consumed*, as it is in a cigarette, and *no ash is formed.*”).

As explained above, Exhibit J details why combustion in IQOS cannot occur—namely because its heater has a built-in temperature ceiling far below the level required for combustion. *Id.* at 40 (temperature in IQOS “cannot exceed 350°C (the programmed maximum temperature of the heater)”). Exhibit J includes experimental data—including the examples summarized below—refuting Plaintiff’s conclusory allegation and demonstrating that no combustion occurs:

- The highest observed temperature of tobacco in the HeatStick after extensive testing was approximately 300°C (and as discussed above, the temperature cannot exceed 350°C).
- Temperature in IQOS dropped during puffs and after device turn-off, the opposite of what would be expected if combustion were occurring.
- The aerosol generated by IQOS in an atmosphere of pure nitrogen (where combustion by definition cannot occur) was equivalent to the aerosol generated in air (21% oxygen).
- IQOS aerosol does not contain solid particles found in smoke.
- IQOS aerosol contains negligible amounts of combustion markers such as nitrogen and carbon monoxide.

Id. at 40-41.

All of the factual assertions recited above appear in an exhibit that is “part of the pleading *for all purposes*.” FED. R. CIV. PROC. 10(c). For that reason, they are considered as part of the Complaint’s substantive factual assertions in evaluating a 12(b)(6) motion. *F.T.C.*, 713 F.3d at 63 (“At the motion-to-dismiss stage, we

consider the facts derived from a complaint’s exhibits as part of the plaintiff’s basic factual averments.”); *see also Tellabs*, 551 U.S. at 322 (courts evaluating a 12(b)(6) motion “must consider...***documents incorporated into the complaint by reference***”). Not only that but where—as is the case here—exhibits contradict assertions in the Complaint, ***the exhibits govern***. *Simmons v. Peavy–Welsh Lumber Co.*, 113 F.2d 812, 813 (5th Cir. 1940) (“Where there is a conflict between allegations in a pleading and exhibits thereto, it is well settled that the exhibits control.”); *Griffin*, 496 F.3d at 1206.

In view of this controlling law, Plaintiff’s infringement claim is deficient as a matter of law. Plaintiff alleges in conclusory fashion that combustion occurs in IQOS, but the very exhibit it cites in support unambiguously states the opposite. As courts have repeatedly held, a complaint that is contradicted by its own exhibits should be dismissed. *See Associated Builders, Inc. v. Alabama Power Co.*, 505 F.2d 97, 100 (5th Cir. 1974) (“If the appended document, to be treated as part of the complaint for all purposes under Rule 10(c), Fed. R. Civ. P., reveals facts which foreclose recovery as a matter of law, dismissal is appropriate.”); *Griffin* 496 F.3d at 1206 (dismissing complaint that was contradicted by exhibit and stating that “when the exhibits contradict the general and conclusory allegations of the pleading, the exhibits govern”). Patent cases, moreover, are no exception to the requirement for

plausible, internally coherent, complaint allegations. *See, e.g., Cumberland Pharms. Inc. v. Innopharma, Inc.*, No. 1:12-cv-00618-LPS, 2013 WL 5945794, at *2-3 (D. Del. Nov. 1, 2013) (dismissing patent infringement claim rendered implausible by complaint allegations); *ecoNeugenics, Inc. v. Bioenergy Life Science, Inc.*, No. 17-cv-5378 (JNE/DTS), 2018 WL 4210198, at *8 (D. Minn. Sept. 4, 2018) (same).

The FDA’s Scientific Review of the MRTPA further confirms the futility of Plaintiff’s conclusory allegation of “combustion.” As noted, the FDA expressly confirmed that no combustion occurs in IQOS: “After conducting a thorough assessment of the scientific evidence, *I find that ‘the IQOS system heats tobacco but does not burn it.’*” FDA Scientific Review at 10. In reaching that conclusion, the FDA validated the MRTPA’s statements about IQOS’s engineered inability to reach combustion temperatures:

The applicant provided detailed information on the verification of heating blade temperature and quantitative thermal analysis using infrared thermography, *demonstrating that the temperature does not exceed 350°C,*” and that “[t]he *combustion of combusted cigarettes typically occurs between 470–812 °C, which is well above the maximum temperature of the IQOS system.*

Id. at 20. Plaintiff should not be allowed to proceed with an infringement theory that cannot prevail.

B. Plaintiff's Implausible Allegations Do Not Change the Analysis

Plaintiff's Complaint alleges that "the presence of 3% of the two important combustion markers nitrogen oxides and carbon monoxide indicates that at least some combustion occurs when the Accused Infringing Product is operated as designed and intended by Defendants." (Doc. 1 ¶46). These allegations do not make Plaintiff's conclusory allegation on combustion sufficiently plausible to survive a motion to dismiss.

First, this assertion is based on the unsupported and implausible assumption that combustion is the only possible explanation for the presence of even trace amounts of these compounds. Exhibit J and the FDA Scientific Review both establish that this assumption is implausible. Specifically, Exhibit J presents experimental data showing that carbon monoxide levels in IQOS aerosol were indistinguishable from background air in four different environments, while nitrogen oxide levels likewise failed to register in three out of four. Doc. 1-10 at 43-44. Further, the FDA found that (1) carbon monoxide was "still present at minimal levels [in IQOS aerosol] because CO can also be formed by thermal decomposition (pyrolysis) of tobacco components," while (2) "the small differences in the level of nitrogen oxides between the nitrogen atmosphere and synthetic air suggest that the

nitrogen oxides are formed mainly by nitrate decomposition and ***not by combustion.***” FDA Scientific Review at 21.

In short, both Exhibit J and the FDA Scientific Review directly refute the inference that trace amounts of these gases is indicative of combustion. This is further reflected in their plain statements—outlined in detail above—that no combustion actually occurs in IQOS. *See, e.g.*, Doc. 1-10 at 19, 23, 40-41; FDA Scientific Review at 10, 20-21.

For these reasons, no deference is due Plaintiff’s implausible allegation. Exhibit J and the FDA Scientific Review (which the Court may judicially notice) confirm that Plaintiff’s “nitrogen oxides and carbon monoxide” allegations establish the absence of combustion – and cannot plausibly support a conclusory allegation of combustion. *See Secured Mail Sols. LLC v. Universal Wilde, Inc.*, 873 F.3d 905, 913 (Fed. Cir. 2017) (“In ruling on a 12(b)(6) motion, a court need not accept as true allegations that contradict matters properly subject to judicial notice or by exhibit...”).

C. Plaintiff Cannot Rely on the Doctrine of Equivalents

The Complaint fails to allege that the absence of combustion is equivalent to combustion. Doc. 1 ¶¶ 46, 52. Regardless, such an allegation would fail as a matter of law because it would effectively read the limitation out of the claim. *Moore*

U.S.A., Inc. v. Standard Register Co., 229 F.3d 1091, 1106 (Fed. Cir. 2000) (holding “that the applicant’s use of the term ‘majority’ is not entitled to a scope of equivalents covering a minority” because “it would defy logic to conclude that a minority—the very antithesis of a majority—could be insubstantially different from a claim limitation requiring a majority....”).

The doctrine of prosecution history estoppel would also bar such an equivalency argument. “Prosecution history estoppel applies as part of an infringement analysis to prevent a patentee from using the doctrine of equivalents to recapture subject matter surrendered from the literal scope of a claim during prosecution.” *Amgen Inc. v. Coherus BioSciences Inc.*, 931 F.3d 1154, 1159 (Fed. Cir. 2019). Here, the patent examiner that allowed the patent specifically identified the “combustion” limitation as her reason for doing so:

Although the prior art teaches an electronic cigarette comprising multiple pipe sections and a heating element; however, the prior art documents teach that electronic cigarettes are intended to mimic the experience of smoking a combustible cigarette without the actual combustion of tobacco. Therefore, the prior art does not teach or suggest an electronic cigarette having a heating element ***initiating a combustion reaction***.

Ex. 2.⁷ Further, in an application to which the '170 Patent claims priority, the applicant expressly distinguished combustion from vaporization to avoid prior art:

Independent claim 1 is not anticipated as *Conley* does not describe a combustible material reservoir nor a heating element that initiates a combustion reaction within the reservoir. ***Conley is directed at a liquid vaporizer, not a combustion device***, and therefore would have no reservoir for combustible material. ***Combustion is a chemical reaction upon heating, whereas vaporization required by Conley is a phase change***. This distinction in purpose and effect dictates the structural differences - *Conley* uses a liquid solution contained in an absorbent material that is in direct contact with a heating coil or wire. The liquid-impregnated absorbent encapsulates the wire and when a charge is applied to the wire, the liquid experiences a phase change to vapor. In the present invention, the reservoir itself is heated by a wire, ***which initiates a combustion reaction*** in the reservoir, which in turn heats combustible material (i.e. tobacco or other dry material) contained in the combustible material reservoir.

⁷ Exhibit 2 is the December 4, 2019 “Notice of Allowance” for App. No. 15/923,848, which issued as the '170 Patent. Exhibit 3 is a November 18, 2016 Amendment and Argument the applicant filed with the Patent Office in App. No. 13/987,851. Both documents are part of the “file history” of each respective application, and are publicly available on the Patent Office website. See <https://portal.uspto.gov/pair/PublicPair>. As with other agency records, courts routinely take judicial notice of Patent Office proceedings. See, e.g., *Kimberly-Clark Corp. v. Extrusion Grp., LLC*, No. 1:18-CV-04754-SDG, 2020 WL 4001129, at *4 n. 29 (N.D. Ga. July 15, 2020) (“The Court may consider the assignment document and inventors’ declaration without converting Kimberly-Clark’s motion into one for summary judgment: ***Both documents are matters of public record filed with the USPTO. Accordingly, the Court may properly take judicial notice of them.***”); *Omnicom Corp. v. AT&T Mobility, LLC*, No. 1-11-CV-4264-AT, 2013 WL 12247764, at *4 n. 9 (N.D. Ga. Apr. 22, 2013) (taking judicial notice of “publicly available patents and patent applications”).

Ex. 3 [App. No. 13/987,851, 11.18.2016 Applicant Argument]. In other words, the applicant unmistakably disclaimed vaporization as a possible equivalent to combustion. Consequently, Plaintiff cannot avoid dismissal based on the doctrine of equivalents. *Accord Amgen*, 931 F.3d at 1161 (“The district court did not err in determining that prosecution history estoppel bars Amgen from succeeding on its infringement claim under the doctrine of equivalents. Accordingly, we affirm the district court's order dismissing Amgen's complaint for failure to state a claim.”).

* * * * *

Plaintiff has presented a claim so implausible that it has pled itself out of court. Because amendment in this case would be futile, dismissal should be with prejudice. The Eleventh Circuit has found that “denial of leave to amend is justified by futility when the complaint as amended is still subject to dismissal.” *Burger King Corp. v. Weaver*, 169 F.3d 1310, 1320 (11th Cir. 1999). Here, no amount of amendments or repleading can change the fact that no combustion occurs in IQOS.

V. PLAINTIFF’S INDIRECT INFRINGEMENT ALLEGATIONS MUST BE DISMISSED

Because the Complaint fails to state a plausible claim for direct infringement, there can be no indirect infringement as a matter of law. *See Dynacore*, 363 F.3d at 1272. Therefore, all allegations of direct infringement and indirect infringement should be dismissed.

Independently, Plaintiff's bare allegations of knowledge, which fail to allege that Defendants ever knew of the existence of the '170 patent, are separately deficient and cannot support a claim for indirect infringement. For example, in *Swipe Innovations*, this district dismissed similar threadbare allegations as failing to provide the requisite pre-suit knowledge. *Swipe Innovations*, 2013 WL 6080439, at *3 (dismissing indirect infringement claims where complaint alleged defendant took steps "to cause infringement with both knowledge of the 296 patent and the specific intent to cause [the infringing acts]"). As this District acknowledged, "[w]ithout supporting fact, this [type of] assertion amounts to speculation that cannot survive a motion to dismiss." *Id.* Because Plaintiff fails to plausibly allege pre-suit knowledge of the '170 patent—let alone knowledge of infringement of the patent—Plaintiff's indirect infringement claims should be dismissed.

VI. CONCLUSION

Defendants respectfully request that the Court grant Defendants' Rule 12(b)(6) Motion and dismiss Plaintiff's Complaint with prejudice.

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Respectfully Submitted,

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7.1(D) CERTIFICATION

Counsel for the Defendant Philip Morris USA, Inc. hereby certifies that this document has been prepared with one of the font and point selections approved by the Court in Local Rule 5.1(C).

/s/ Charles A. Pannell, III

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CERTIFICATE OF SERVICE

I hereby certify that on February 25, 2021, a copy of the foregoing was filed with the Clerk of Court using CM/ECF which will send electronic notification of such filing to all counsel of record.

/s/ Charles A. Pannell, III

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